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On 12/09/02

TOWNSEND and TOWNSEND and CREW LLP

By: MAIHAN VO

PATENT
Attorney Docket No.: 015270-006446US
Client Reference No.: 228-US-NEW2C6

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

John P. Anderson et al.

Application No.: 09/724,569

Filed: November 28, 2000

For: BETA-SECRETASE ENZYME COMPOSITIONS AND METHODS

Examiner: Unknown

Art Unit: 1632

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.97 and §1.98

Technology Center 1600
Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

The references cited on attached PTO/SB/08A and PTO/SB/08B forms are being called to the attention of the Examiner. In accordance with 37 CFR §1.98(d), copies of the references can be found in Application No. 09/471,669, filed December 24, 1999 (Attorney Docket No. 015270-006430US). It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

Cite no. 78 is a copy of the International Search Report issued for the corresponding International application, PCT/US00/03819. Cite No. 65 is a copy of a press release announcing that Elan Corporation, plc and Pharmacia Corporation entered into a research collaboration focused on the discovery of small molecule inhibitors of beta-secretase for the

treatment of Alzheimer's disease. Elan Pharmaceuticals, Inc. assignee of the instant application, is affiliated with Elan Corporation, plc.

Applicants also cite commonly owned copending applications and issued patents directed to related subject matter:

08/480,498, filed 06/07/95, issuing as US Patent 5,744,346 on April 28, 1998;

08/485,152, filed 06/07/95;

08/659,984, filed 06/07/96, issuing as US Patent 5,942,400 on August 24, 1999;

08/660,531, filed 06/07/96, issuing as US Patent 6,221,645 on April 24, 2001;

09/054,334, filed 04/02/98, issuing as US Patent 6,329,163 on December 11, 2001;

09/404,578, filed 09/23/99;

09/471,669, filed 12/24/99;

09/501,708, filed 02/10/00;

09/723,722, filed 11/28/00;

09/723,739, filed 11/28/00;

09/724,568, filed 11/28/00;

09/724,566, filed 11/28/00;

09/724,569, filed 11/28/00;

09/724,571, filed 11/28/00; and,

10/099,922, filed 03/15/02;

Applicants further cite the following commonly owned abandoned applications directed to related subject matter:

60/114,408, filed 12/31/98;

60/119,571, filed 02/10/99;

60/139,172, filed 06/15/99;

60/168,854, filed 12/02/99; and,

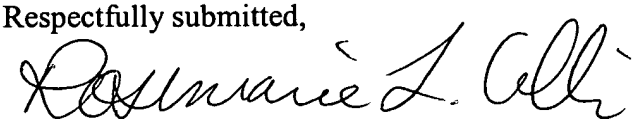
09/730,329, filed 12/04/00.

As provided for by 37 CFR 1.97(g) and (h), no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information, and no inference should be made that the information and references cited are, or are considered to be material to patentability because they are in this statement. No inference

should be made that the information and references cited are prior art merely because they are in this statement.

Applicant believes that no fee is required for submission of this statement. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,



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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 6

Complete if Known	
Application Number	09/724,569
Filing Date	November 28, 2000
First Named Inventor	John P. Anderson
Art Unit	1632
Examiner Name	Unknown
Attorney Docket Number	015270-006446US

U.S. PATENT DOCUMENTS					
Examiner	Cite No.[1]	Document Number Number Kind Code[2] (*if known*)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1	6,361,975	03-26-2002	Christie, et al.	
	2	6,358,725	03-19-2002	Christie, et al.	
	3	6,319,489	11-20-2001	Powell, et al.	
	4	6,319,689	11-20-2001	Powell, et al.	
	5	6,313,268	11-06-2001	Hook	
	6	6,245,884	06-12-2001	Hook	
	7	6,245,964	06-12-2001	McConlogue, et al.	
	8	6,221,645	04-24-2001	Chrysler, et al.	
	9	6,211,428	04-03-2001	Singh, et al.	
	10	6,162,630	12-19-2000	Powell, et al.	
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	12	5,942,400	08-24-1999	Anderson, et al.	
	13	5,877,015	03-02-1999	Hardy, et al.	
	14	5,849,560	12-15-1998	Abraham	
	15	5,837,672	11-17-1998	Schenk, et al.	
	16	5,795,963	08-18-1998	Mullan	
	17	5,766,846	06-16-1998	Schlossmacher, et al.	
	18	5,750,349	05-12-1998	Suzuki, et al.	
	19	5,744,346	04-28-1998	Chrysler, et al.	
	20	5,733,768	03-31-1998	Dixon, et al.	
	21	5,593,846	01-14-1997	Schenk, et al.	
	22	5,455,169	10-03-1995	Mullan	
	23	5,424,205	06-13-1995	Dovey, et al.	
	112	09/869,414		Gurney, et al.	
	90	09/794,927		Gurney, et al.	
	91	09/794,925		Gurney, et al.	

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Sheet 2 of 6

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Art Unit	1632
Examiner Name	Unknown
Attorney Docket Number	015270-006446US

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	89	09/795,847	NA	Gurney, et al.	
	92	09/794,748		Gurney, et al.	
	88	09/794,743		Gurney, et al.	
	111	09/681,442		Gurney, et al.	
	87	09/551,853		Gurney, et al.	
	96	09/548,376		Gurney, et al.	
	24	09/548,373		Gurney, et al.	
	99	09/548,372		Gurney, et al.	
	94	09/548,370		Gurney, et al.	
	97	09/548,369		Gurney, et al.	
	100	09/548,368		Gurney, et al.	
	98	09/548,367		Gurney, et al.	
	25	09/548,366		Gurney, et al.	
	95	09/548,365		Gurney, et al	
	26	09/416,901		Gurney, et al.	
	27	09/404,133		Gurney, et al.	
	28	09/277,229		Citron, et al.	
	29	60/210,292		Hong, et al.	
	30	60/178,368		Lin, et al.	
	31	60/177,836		Lin, et al.	
	32	60/168,060		Lin, et al.	
	33	60/155,493		Gurney, et al.	
	34	60/141,363		Lin, et al.	
	35	60/139,172		Anderson, et al.	
	36	60/119,571		Basi, et al.	
	37	60/114,408		Basi, et al.	
	38	60/101,594		Gurney, et al.	

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Sheet 3 of 6

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Application Number	09/724,569
Filing Date	November 28, 2000
First Named Inventor	John P. Anderson
Art Unit	1632
Examiner Name	Unknown
Attorney Docket Number	015270-006446US

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document: Country Code[3]	Foreign Patent Document: Number[4]	Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	39	EP	EP 0 855 444	A2	07-29-1998			
	40	EP	EP 0 848 062	A2	06-17-1998			
	48	PCT	WO 01/38487	A2	05-31-2001			
	49	PCT	WO 01/36600	A1	05-25-2001			
	50	PCT	WO 01/31054	A1	05-03-2001			
	51	PCT	WO 01/29563	A1	04-26-2001			
	52	PCT	WO 01/00665	A2	01-04-2001			
	53	PCT	WO 01/00663	A2	01-04-2001			
	47	PCT	WO 00/69262	A1	11-23-2000			
	46	PCT	WO 00/68266	A1	11-16-2000			
	45	PCT	WO 00/58479	A1	10-05-2000			
	44	PCT	WO 00/56871	A2	09-28-2000			
	43	PCT	WO 00/47618	A3	08-17-2000			
	42	PCT	WO 00/23576	A2	04-27-2000			
	41	PCT	WO 00/17369	A2	03-30-2000			
	54	PCT	WO 99/64587	A1	12-16-1999			
	55	PCT	WO 99/46281	A2	09-16-1999			
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	59	PCT	WO 99/31236	A2	06-24-1999			
	60	PCT	WO 98/26059		06-18-1998			
	61	PCT	WO 98/21589		05-22-1998			
	62	PCT	WO 98/13488		04-02-1998			
	63	PCT	WO 98/11236		03-19-1998			
	103	PCT	WO 97/47314		12-18-1997			
	56	PCT	WO 96/40885	A2	12-19-1996			
	58	PCT	WO 96/31122	A1	10-10-1996			
	102	PCT	WO 96/20725	A2	07-11-1996			

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Sheet 4 of 6

Complet if Known	
Applicati n Number	09/724,569
Filing Date	November 28, 2000
First Named Inventor	John P. Anderson
Art Unit	1632
Examiner Name	Unknown
Attorney Docket Number	015270-006446US

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	104	Baldwin, et al., Crystal structures of native and inhibited forms of human cathepsin D: Implications for lysosomal targeting and drug design, *PNAS USA*, 90:6796-6800 (1993).	
	105	Brown, et al., Evaluation of Cathepsins D and G and EC 3.4.24.15 as Candidate β-Secretase Proteases Using Peptide and Amyloid Precursor Protein Substrates, *Journal of Neurochemistry*, 66: 2436-2445 (1996).	
	106	Chevallier, et al., Cathepsin D displays in vitro β-secretase-like specificity, *Brain Research*, 750:11-19 (1997).	
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	65	Elan Corporation, plc and Pharmacia Corporation announce research collaboration, News 08/09/2000, www.elancorp.com.	
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	67	Haass, et al., Amyloid β-peptide is Produced by Cultured Cells During Normal Metabolism, *Nature*, 359: 322-325 (September 24, 1992).	
	68	Haass, et al., The Swedish Mutation Causes Early-Onset Alzheimer's Disease by β-Secretase Cleavage Within the Secretory Pathway, *Nature Medicine*, 12: 1291-1296 (December 1995).	
	69	Haass, et al., β-Amyloid Peptide and 3-kDa Fragment are Derived by Distinct Cellular Mechanisms, *Journal of Biochemistry*, 268: 3021-3024 (February 15, 1993).	
	70	Hirosawa, et al., Characterization of cDNA Clones Selected by the GeneMark Analysis from Size-Fractionated cDNA Libraries From Human Brain, *DNA Res.*, 6(5): 329-336 (October 29, 1999).	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 5 of 6

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Application Number	09/724,569
Filing Date	November 28, 2000
First Named Inventor	John P. Anderson
Art Unit	1632
Examiner Name	Unknown
Attorney Docket Number	015270-006446US

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	71	Hussain, et al., Identification of a Novel Aspartic Protease (Asp 2) as β-Secretase, *Molecular and Cellular Neuroscience,* 14: 419-427 (1999).	
	72	Kang, et al., The Precursor of Alzheimer's Disease Amyloid A4 Protein Resembles a Cell-Surface Receptor, *Nature*, 325: 733-736 (February 19, 1987).	
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	77	PCT Search report for PCT/US99/20881	
	78	PCT Search report for PCT/US00/03819	
	79	Ponte, et al., A New A4 Amyloid mRNA Contains a Domain Homologous to Serine Proteinase Inhibitors, *Nature*, 331: 525-527 (February 11, 1988).	
	109	Saftig, et al., Amyloidogenic Processing of Human Amyloid Precursor Protein in Hippocampal Neurons Devoid of Cathepsin D, *Journal of Biological Chemistry*, 271:27241-27244 (1996).	
	110	Schechter, et al., On the size of the active site in proteases. I. Papain, *Biochemical and Biophysical Research Communications*, 27:157-162 (1967).	

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Sheet 6 of 6

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	80	Seubert, et al. Secretion of β-amyloid Precursor Protein Cleaved at the Amino Terminus of the β-amyloid Peptide, *Nature*, 361: 260-263 (January 21, 1993).	
	81	Sinha, et al., Purification and Cloning of Amyloid Precursor Protein β-Secretase from Human Brain, *Nature*, 402: 537-540 (December, 2 1999).	
	82	Szecsi, The Aspartic Proteases, *Scand. J. Clin. Lab. Invest.*, 52 (suppl. 210): 5-22 (1992).	
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	93	Thompson, et al., Expression and characterization of human β-secretase candidates metalloendopeptidase MP78 and cathepsin D in βAPP-overexpressing cells, *Molecular Brain Research*, 48:206-214.	
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	101	Young, et al., HIV-1 Protease Inhibitors Based on Hydroxyethylene Dipeptide Isosteres: An Investigation into the Role of the P_1-Side Chain on Structure-Activity, *J. Med. Chem.*, 35:1702-1709 (1992).	
	86	Zhao, et al., β-Secretase Processing of the β-Amyloid Precursor Protein in Transgenic Mice Is Efficient in Neurons but Inefficient in Astrocytes, *Journal of Biological Chemistry*, 271: 31407-31411 (December 6, 1996).	

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